

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	Gerd Beck, <i>et al.</i>
Serial No. - Pending	Filing Date: June 1, 2001
Title of Application	Testing Or Setting Device For A PDD Or PDT System, Or For Training On Such A System And Tissue Phantom

Assistant Commissioner for Patents  
Washington, DC 20231

**Preliminary Amendment**

Dear Sir:

Please enter this preliminary amendment before examination of this case.

In the Claims

4. Device according to [one of Claims 1 to 3] Claim 1, characterized in that a sterile foil protects the sterile portion from contamination upon each introduction of a sterile portion.
5. Device according to [one of Claims 1 to 4] Claim 1, characterized in that the tissue phantom is secured on a movable holder.
6. Device according to [one of Claims 1 to 5] Claim 1, characterized in that the tissue phantom is secured in the housing in such a way that it can be exchanged.
7. Device according to [one of Claims 1 to 6] Claim 1, characterized in that several tissue phantoms are installed in the housing.
8. Device according to [one of Claims 1 to 7] Claim 1, characterized in that the tissue phantom copies the optical, thermal, electrical, or mechanical characteristics of a particular human or animal tissue or organ.
10. Device according to [one of Claims 1 to 9] Claim 1, characterized in that the portion of the tissue phantom that is to be illuminated by the lighting system is shaped in such a way that the surface shape of a certain tissue area is copied.

12. Device according to one of [Claims 1 to 11] Claim 1, characterized in that a filter system or additional lighting system is provided, through which the emission spectrum of the tissue phantom is adjusted in vivo to the emission spectrum of a particular bodily tissue.
13. Testing or setting device for a PDD or PDT system, which includes a lighting system and an observation system, characterized by the following steps:
- The PDD or PDT system to be tested or set is at least partially accommodated in a housing or device in accordance with [one of Claims 1 to 12] Claim 1;
  - the surface of the tissue phantom is at least partially illuminated by the lighting system;
  - the illuminated surface of the tissue phantom is at least partially observed by the observation system;
  - at least one measurement or one observation result is recorded, which is a measurement for the luminescent intensity or for the reporting sensitivity or functionality of the PDD or PDT system; and
  - if necessary a corrective adjustment of the PDD or PDT system will be made.
14. Tissue phantom to be used in a device in accordance with [one of Claims 1 to 12] Claim 1, which tissue phantom includes at least a first luminescent area, characterized in that it has at least one additional area, whose luminescent properties are distinguished from those of the first luminescent area.
17. Tissue phantom according to [one of Claims 14 to 16] Claim 14, characterized in that the tissue phantom contains at least two areas with graduated luminescent intensity, so that for at least one of these areas the luminescent intensity is selected in such a way that the recognition of this area can permit the determination of the functionality of a PDD or PDT system.
20. Device according to [one of Claims 1 to 12] Claim 1, characterized in that a tissue phantom in accordance with [one or more of Claims 13 to 17] Claim 13 is used.

Respectfully submitted,



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Replacement claims per §1.121 (c) (30):

1. Testing or setting device for a PDD or PDT system or for training on such a system, which includes a lighting system
  - where the device is provided with a housing in which the PDD or PDT system can be at least partially accommodated, characterized in that
  - a tissue phantom is accommodated in the housing in such a way that the surface of the tissue phantom can be at least partially illuminated by the lighting system and
  - the tissue phantom has at least one luminescent area.
2. Device according to Claim 1, characterized in that the housing has a hollow area in which the PDD or PDT system for testing, setting, or training can be at least partially accommodated.
3. Device according to Claim 2, characterized in that the hollow area is closed off and has at least one aperture equipped with a sealing device to accommodate part of the PDD or PDT system.
4. Device according to Claim 1, characterized in that a sterile foil protects the sterile portion from contamination upon each introduction of a sterile portion.
5. Device according to Claim 1, characterized in that the tissue phantom is secured on a movable holder.
6. Device according to Claim 1, characterized in that the tissue phantom is secured in the housing in such a way that it can be exchanged.
7. Device according to Claim 1, characterized in that several tissue phantoms are installed in the housing.
8. Device according to Claim 1, characterized in that the tissue phantom copies the optical, thermal, electrical, or mechanical characteristics of a particular human or animal tissue or organ.
9. Device according to Claim 8, characterized in that the portion of the tissue phantom that is to be illuminated by the lighting system copies colors and luminescent characteristics of a particular tissue area.
10. Device according to Claim 1, characterized in that the portion of the tissue phantom that is to be illuminated by the lighting system is shaped in such a way that the surface shape of a certain tissue area is copied.

11. Device according to Claim 10, characterized in that the portion of the tissue phantom that is to be illuminated by the lighting system has the shape of a hollow sphere or tube.
12. Device according to Claim 1, characterized in that a filter system or additional lighting system is provided, through which the emission spectrum of the tissue phantom is adjusted in vivo to the emission spectrum of a particular bodily tissue.
13. Testing or setting device for a PDD or PDT system, which includes a lighting system and an observation system, characterized by the following steps:
  - the PDD or PDT system to be tested or set is at least partially accommodated in a housing or device in accordance with Claim 1;
  - the surface of the tissue phantom is at least partially illuminated by the lighting system;
  - the illuminated surface of the tissue phantom is at least partially observed by the observation system;
  - at least one measurement or one observation result is recorded, which is a measurement for the luminescent intensity or for the reporting sensitivity or functionality of the PDD or PDT system; and
  - if necessary a corrective adjustment of the PDD or PDT system will be made.
14. Tissue phantom to be used in a device in accordance with Claim 1, which tissue phantom includes at least a first luminescent area, characterized in that it has at least one additional area, whose luminescent properties are distinguished from those of the first luminescent area.
15. Tissue phantom according to Claim 14, characterized in that in at least one luminescent area the luminescence is dimmed through the action of a lighting device.
16. Tissue phantom according to Claim 15, characterized in that a means is provided for introducing an oxygen-containing solution of a photo-sensitizer into the tissue phantom.
17. Tissue phantom according to Claim 14, characterized in that the tissue phantom contains at least two areas with graduated luminescent intensity, so that for at least one of these areas the luminescent intensity is selected in such a way that the recognition of this area can permit the determination of the functionality of a PDD or PDT system.
18. Device for producing a tissue phantom, characterized by the following steps:
  - A first tissue phantom material is cast in a mold which contains one or more depths set off from one another or connected with one another, and a thin layer beyond the individual depths links them to one another;
  - the first material is hardened;

- the mold is removed from the cast and laid on its surface;
  - a second phantom tissue is poured into the depths of the case, which phantom tissue has luminescent characteristics that differ from those of the first material.
19. Tissue phantom with at least one luminescent area, characterized in that the one or more luminescent areas consist of a silicon with the following additions:
- 0.5% to 10%, preferably 2% to 7%, a substance of the ZnO group, BaSO<sub>4</sub>, AL<sub>2</sub>O<sub>3</sub>, MgO, or other colorless oxides as powder,
  - less than 1%, an organic or inorganic pigment, and
  - less than 2%, fluorescent particles instilled with coloring agent.
20. Device according to Claim 1, characterized in that a tissue phantom in accordance with Claim 13.